

REMARKS/ARGUMENTS

Claims 1 and 7 are amended. Claims 1 - 20 are still pending.

Entry of the amendments of claims 1 and 7 is considered proper under 37 CFR § 1.116, because they are believed to put the application in condition for allowance, do not raise any new matter that would require further consideration on the merits, and put the claims in better form for appeal, if necessary. Furthermore, the amendments are intended to clarify the invention recited in the claims, the ambiguity of which was only first raised in the final rejection. In fact, the examiner explicitly suggests that the claims be amended, at page 7 of the Office Action dated June 6, 2003.

Examiner Gollamudi and Primary Examiner Hartley are thanked for the helpful discussion that took place during the interview on November 20, 2003 with the undersigned and Dr. Padmanabh Bhatt of Shire Laboratories, Inc. Applicants' separate record of the substance of the interview is presented herein.

It was apparent at the interview that the rejections were maintained because of a possible alternative interpretation of the claims. That is, it was the examiner's position that the claims could be interpreted to include a semi-permeable wall between the "core" and "layer" portions of the osmotic system, and that the claims do not preclude such a wall. It was and is Applicants' position that a fair reading of the entire application would lead one skilled in the art to the understanding that the layer portion *immediately*

surrounds the core portion, and that the semi-permeable wall surrounds the layer portion; i.e., there is only one wall, and that it is exterior to the layer portion.

To the extent that the main claims 1 and 7 could be construed as open to the possibility of a semipermeable wall between the core and the layer portion, Applicants have amended them to exclude such an embodiment by reciting that the layer portion is "directly adjacent to" the core portion. It is believed that this language clarifies the nature of the invention. Applicants' first suggestion at the interview of adding "single" to the preamble, to recite a single osmotic system, is obviated by the "directly adjacent to" language in the body of the claims.

Support for the amendments to claims 1 and 7 is found throughout the specification, for instance: throughout the specification and claims, the semipermeable wall was consistently referred to in the singular ("the", "a"); the drawing depicts (and the accompanying description on page 7, third full paragraph refers to) only one semipermeable wall (16), which is shown in its position outside of the layer portion (14); at page 4, first sentence of the second paragraph, where it is stated that the therapeutic agent is contained *wholly* within *the* semipermeable wall; and Example 1, wherein it is described that the tableted core is coated with the drug layer, followed by coating with the semipermeable wall ("applied after the drug layer").

Applicants believe it is proper to enter the amendment, particularly because this is not a matter of narrowing a claim to exclude certain embodiments in order to distinguish from the prior art; it is merely a matter of clarifying what Applicants regard as their invention. Entry of the amendments is earnestly solicited.

The Office Action maintained three of the four obviousness rejections made in the first action, and added a new rejection of claim 20. Applicants traverse each of these rejections.

First, claims 1 -5 and 7 - 16, 18 and 19 stand rejected over Faour et al. (6,491,949), alone.

In response to Applicants' previous arguments, the examiner states that Faour was applied to reject these claims on the basis that the claims, as they had appeared before, did not exclude an additional semi-permeable wall in the recited osmotic dosage system. With the amendments to claims 1 and 7, this rejection is obviated. The dual osmotic system of Faour simply is not instructive or suggestive of the system of the present claims, which do not allow for a semipermeable wall between the core and layer portions of the dosage unit. Accordingly, this rejection should be withdrawn.

Second, claims 6, 17 and 20 were rejected as obvious over Faour in view of Hamel (4,801,461). This rejection is also traversed.

On the same basis as above, and for reasons previously stated on the record, the Faour patent does not render the present claims obvious. Hamel

does not make up for the deficiencies of Faour. The combined references cannot support a *prima facie* case of obviousness. Withdrawal is respectfully requested.

Third, claims 1 - 6 and 12 - 14 stand rejected as being allegedly obvious over Savastano in view of Faour (6,004,582). This rejection is also traversed.

The examiner states that the claims, as they previously stood, did not exclude a delay jacket, as taught in Savastano. With the present amendments, this rejection is obviated, because the primary reference does not disclose or suggest a system without said delay jacket. Faour '582 does not overcome the shortcomings of the Savastano patent. Thus, on the basis of the arguments of record and the amendments herein, withdrawal is deemed proper.

Finally, claim 20 was newly rejected under 35 USC § 103 over Faour '949 in view of Weinstein '585. This rejection is traversed.

Weinstein is newly cited for its teaching of a decongestant and an antihistamine in a single composition. However, for the reasons cited above with respect to the primary reference, Faour '949, the presently amended claims no longer "read on" a dual osmotic system such as that taught in Faour. Thus, dependent claim 20 cannot be held obvious in view of this combination of references.

Applicants respectfully submit that the claims in their amended form are new and unobvious over the art. Accordingly, Applicants respectfully submit that this application is in condition for allowance. If there are any matters remaining

S rial No. 09/872,173

Pag 11 of 11

Expr ss Mail No. EU359845354US

that could best be resolved by telephone, the examiner is invited to contact the undersigned at the number listed below.

This paper is being filed with a Petition for Three Month Extension of Time, as well as a Notice of Appeal.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'MEL' or similar, written in a cursive style.

Mary Elisa Lane
Registration No. 34,409
Attorney for Applicants

SHIRE LABORATORIES INC.
1550 East Gude Drive
Rockville, MD 20850
Tel: 301/838-2658
Fax: 301/838-2501
Email: mlane@shirelabs.com